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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

AMY MAXWELL, individually and on behalf of all others similarly situated,

Plaintiff,

v.

UNILEVER UNITED STATES, INC., PEPSICO, INC., and PEPSI LIPTON TEA PARTNERSHIP,

Defendants.

Case No. CV12-01736-EJD

REPLY IN SUPPORT OF DEFENDANTS UNILEVER UNITED STATES, INC. AND PEPSI/LIPTON TEA PARTNERSHIP'S MOTION TO DISMISS THE FIRST AMENDED COMPLAINT OR, IN THE ALTERNATIVE, MOTION TO STRIKE

Hearing Date: December 7, 2012
Time: 9:00 a.m.
Judge: Hon. Edward J. Davila
Action Filed: April 6, 2012

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I. INTRODUCTION

Briefing can sometimes focus the issues, and so it has here.

First, this is a no-injury case. Plaintiff does not allege that the Defendants' products were defective, tainted, adulterated, inedible, unfit for consumption, or that the contents were misdescribed. Instead, she says products she bought (and many she didn't buy) are "legally worthless" because of FDA regulatory infractions in statements on product labels or websites. But "regulatory injury" cannot stand in place of Article III's "injury in fact" requirement.

Plaintiff cites to the Court's decision in *Khasin v. Hershey*. However, in doing so, she overlooks the difference between *statutory* standing under the UCL, and the Constitutional requirement of an actual, concrete, and particularized injury for purposes of Article III.[1] State law cannot define constitutional standing. That aside, Plaintiff's allegations of "economic injury"—that she paid an undisclosed "premium" for products she would not have purchased had she known the "truth"—fall short of Rule 8 requirements, let alone Rule 9(b).

Second, Plaintiff's claims are inherently implausible. Class counsel told the New York Times, "we researched [FDA] regulations and labels for two years before filing our first case."[2] If it took nine law firms two years of legal research to manufacture claims, how does Plaintiff suppose a "reasonable consumer," let alone the entire class, could attain that level of understanding of FDA rules, so as to have been duped by alleged technical FDA infractions? Plaintiff's novel theory of "regulatory injury" is facially flawed, and no additional facts can turn her legally inadequate allegations into cognizable claims.

Third, Plaintiff fails to plead her claims with the specificity required by Rule 9(b). Hiding behind a façade of regulatory minutiae, she fails to allege the facts necessary to plead her claims.

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[1] *See Khasin v. Hershey Co.*, No. 5:12-CV-01862 EJD, 2012 U.S. Dist. LEXIS 161300, at *17-20 (N.D. Cal. Nov. 9, 2012).

[2] Stephanie Strom, *Lawyers from Suits Against Big Tobacco Target Food Makers*, N.Y. TIMES, Aug. 18, 2012, *available at* http://www.nytimes.com/2012/08/19/business/lawyers-of-big-tobacco-lawsuits-take-aim-at-food-industry.html (Ex. A).

Fourth, Plaintiff seeks to enforce labeling requirements that are "not identical" to federal law. Furthermore, she has no private right of action to enforce technical FDA regulations that are entirely unrelated to consumer deception.

Fifth, all of Plaintiff's individual claims fail for claim-specific reasons.

Ms. Maxwell's claims fail for threshold legal reasons that may properly be decided on a motion to dismiss and strike. The Court should grant Defendants' motion with prejudice.

II. ARGUMENTS IN REPLY

A. Plaintiff Cannot Satisfy Article III's "Case or Controversy" Requirement.

1. This Is a "No-Injury" Case that Fails the Test of Article III.

This is a no-injury case. The heart of Plaintiff's FAC is that Defendants' products are "legally worthless" in light of alleged, hyper-technical violations of FDA regulations. (*See,* FAC ¶ 64.) Her conclusory assertions that she paid a "premium" and would not have purchased the products "had she known the truth" about them are inadequate to satisfy constitutional standing requirements. Plaintiff relies on *Khasin*, 2012 U.S. Dist. LEXIS 161300, at *17-20, to argue otherwise, but in doing so, overlooks the distinction between Article III and statutory standing, which is at odds with opinions by Judges Illston and Wilken in similar "misbranding" cases.

In *Boysen v. Walgreen Co.*, plaintiffs claimed "injury in fact" because juice contained trace amounts of lead and arsenic. Just like Ms. Maxwell, they alleged that "if they had known the products contained lead, they would not have purchased them." No. C 11-06262 SI, 2012 U.S. Dist. LEXIS 100528, at *10-11 (N.D. Cal. July 19, 2012). Finding plaintiffs made no claim that the products "were unfit for their intended use, i.e. consumption," Judge Illston dismissed the claims for lack of Article III standing. *Id.* at *21-22 (citations omitted). Like the *Boysen* plaintiffs, Ms. Maxwell received exactly what she paid for. She alleges no *facts* that suggest otherwise. *Id.* at *11 (allegation of economic injury that "lacks substance" must be dismissed).

Judge Wilken applied the same logic in *Herrington v. Johnson & Johnson Consumer Cos.* to dismiss claims alleging economic injury because bath products contained potentially toxic chemicals. No. C 09-1597 CW, 2010 U.S. Dist. LEXIS 90505, at *17-18 (N.D. Cal. Sept. 1, 2010). Like Ms. Maxwell, the plaintiffs alleged that they would not have purchased the products

had they known they contained such chemicals. *Id.* Judge Wilken found plaintiffs lacked Article III standing, noting that they did not allege the products were unfit for use or that they had not enjoyed the benefit of their bargain. *Id.* at *18. Ms. Maxwell also enjoyed the benefit of her bargain when she bought and consumed Defendants' products: there was no difference between the products advertised and the products she purchased. Unlike the adulteration or "hidden ingredient" cases she relies on,[3] Ms. Maxwell got exactly what she paid for.

Plaintiff attempts to distinguish these cases by confusing and conflating Article III standing with the independent standing requirements that are imposed by California's UCL. For example, *Chavez v. Blue Sky Natural Beverage Co.*, 340 F. App'x 359 (9th Cir. 2009), never even mentions Article III standing, analyzing instead whether plaintiff stated a claim for purposes of Rule 12(b)(6) based on UCL and CLRA requirements. The requirements of state law cannot dictate Article III standing. Even UCL claims "must meet the stricter federal standing requirements of Article III." *Boysen*, 2012 U.S. Dist. LEXIS 100528, at *10 (quoting *Cantrell v. City of Long Beach*, 241 F.3d 674, 683 (9th Cir. 2001)); *see also Birdsong v. Apple*, 590 F.3d 955, 960 n.4 (9th Cir. 2009) (plaintiff alleging UCL claim must also satisfy Article III standing). The courts in *Astiana v. Ben & Jerry's Homemade, Inc.*, No. C 10-4387 PJH, 2011 U.S. Dist. LEXIS 57348, at *12-13 (N.D. Cal. May 26, 2011), and *Carrea v. Dreyer's Grand Ice Cream, Inc.*, No. 10-01044, 2011 U.S. Dist. LEXIS 6371, at *3-4 (N.D. Cal. Jan. 10, 2011), similarly erred by conflating Constitutional and state statutory standing requirements.

Plaintiff's other authorities are factually distinguishable. *Chavez*, 340 F. App'x at 361 (products were not manufactured in New Mexico as stated), and *Carrea*, 2011 U.S. Dist. LEXIS 6371, at *2-3 (front label claims allegedly representing product was "healthy" were belied by nutrition facts panel) are both "bait-and-switch" cases. The ***products were different*** than what the

[3] *Steroid Hormone Product Cases*, 181 Cal. App. 4th 145 (2010) was not about Article III, and involved failure to disclose the presence of illegal steroids. The problem was not the label but the *ingredient*, which was unlawful without a prescription. *United States v. Gonzalez-Alvarez*, 277 F.3d 73 (1st Cir. 2002) was a criminal case in which milk was adulterated with contaminated water and salt. *Thomas v. Imbriolo*, No. A130517, 2012 Cal. App. Unpub. LEXIS 3111, at *21-22 (Apr. 25, 2012) was an appeal of a jury's calculation of a product's market value.

labels promised. And plaintiffs in *Astiana v. Ben & Jerry's* alleged the product was processed with an *undisclosed* ingredient.[4] 2011 U.S. Dist. LEXIS 57348, at *12-13.

Even assuming Article III and state statutory standing requirements are the same, her conclusory assertions of "economic injury" do not satisfy Rule 8, let alone Rule 9(b). Plaintiff has the burden of "alleging ***specific facts*** sufficient to satisfy" Article III standing. *Schmier v. United States Court of Appeals*, 279 F.3d 817, 821 (9th Cir. 2002) (emphasis added). She provides only boilerplate statements that she paid a "premium" for products she would not have purchased had she known the "truth" about them. (FAC ¶ 129.) But she provides no specific facts regarding the "premium," such as how much and as compared to what. If such bare-bones allegations were sufficient, anyone could bring a cognizable claim based on buyer's remorse. Moreover, her claim is belied by the fact that the product labels describe exactly the product that was sold. There is no "increment" or difference in value that would give rise to economic injury.

Nor do Plaintiff's allegations of "regulatory injury" satisfy standing under her state statutory claims. Again, she relies primarily on "bait-in-switch" cases that lend her no support. As with *Chavez, Kwikset Corp. v. Superior Court*, 51 Cal. 4th 310, 317-18 (2011), addressed allegations that a product was different than what the label promised ("Made in U.S.A." label misleading when product contained parts from Taiwan or was assembled in Mexico). That is not true here. In fact, Plaintiff never alleges that *any* of Defendants' products contained ingredients different than what the labels described.[5] Unlike a label falsely stating that a product was "Made in the USA," Defendants' Green Tea label, for example, truthfully states that the tea has "130 mg tea flavonoids per serving." (Mem., 4:25-5:2.) It is implausible that a reasonable consumer would be misled based on interpretations of regulations rather than labels. *See* Section B; *Reid v.*

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[4] In a similar, but more recent, case raising the same "all natural" issue, the same judge granted a motion to dismiss. *See Astiana v. Hain Celestial Grp., Inc.*, No. C 11-6342 PJH, --F. Supp. 2d--, 2012 U.S. Dist. LEXIS 165368 (N.D. Cal. Nov. 19, 2012) (Ex. B).

[5] *Degelmann v. Advanced Medical Optics Inc.*, 659 F.3d 835 (9th Cir. 2011), was vacated by the Ninth Circuit on October 30, 2012 and is no longer good law. *Degelmann*, No. 10-15222, 2012 U.S. App. LEXIS 22361 (9th Cir. Oct. 30, 2012). Regardless, that case involved a product marketed as "an effective contact lens disinfectant and cleaner," but users were seven times more likely to suffer a serious eye infection. *Degelmann*, 659 F.3d at 838.

Johnson & Johnson, No. 11cv1310 L (BLM), 2012 U.S. Dist. LEXIS 133408, at *12 (S.D. Cal. Sept. 18, 2012) (UCL, FAL, and CLRA claims dismissed where plaintiff "ha[d] not set forth alleged facts showing that [defendant's] statements may deceive a reasonable consumer").

2. The Court Should Dismiss All Claims Concerning Products Plaintiff Did Not Buy.

Plaintiff cannot sue over a host of Defendants' products she never purchased—she lacks standing to bring such claims. Indeed, she cannot argue that she would not have purchased products or that she paid a premium for them when she *never* purchased them in the first place. Since Plaintiff paid no money for these products, there is no economic injury. Relying on *Khasin*, Plaintiff argues that these issues are better addressed at class certification. *Khasin*, 2012 U.S. Dist. LEXIS 161300, at *27. But Rule 23 does not confer or expand Article III standing that a claimant does not otherwise have. Had Ms. Maxwell sued individually, she could sue only over products she bought, not for "similar" products someone else bought. Standing is a threshold issue, and a named plaintiff must have Article III standing in her own right before she can seek to vindicate the rights of others. *See Ellis v. Costco Wholesale Corp.*, 657 F.3d 970, 978 (9th Cir. 2011). Accordingly, this determination can be made on a motion to dismiss.

Plaintiff's attempt to justify her claims by saying that the products she did purchase have "sufficient similarity" to those she did not fails. (Opp., 25:11-15.) In *Astiana v. Ben & Jerry's*, all the cartons of chocolate flavored ice cream in issue said "all natural" on the label and all were alleged to have improperly included the same undisclosed ingredient, potassium carbonate. Here, Plaintiff seeks to sue over *six different* regulatory violations, each potentially affecting different products and advertising that she declines to identify. She should not be permitted to do so. *See Stephenson v. Neutrogena Corp.*, No. C 12-0426 PJH, 2012 U.S. Dist. LEXIS 105099 (N.D. Cal. July 27, 2012) (finding "Neutrogena Natural" products too dissimilar); *Carrea*, 2011 U.S. Dist. LEXIS 6371, at *7-8 (dismissing claims regarding different products). Further, while Plaintiff alleges Defendants' statements "are part of an extensive labeling, advertising and marketing campaign" (FAC ¶ 157), she fails to allege she was exposed to this alleged campaign. *Cf. In re Tobacco II Cases*, 46 Cal. 4th 298, 312 (2009).

B. Plaintiff's Claims Fail Because They Are Facially Implausible.

Plaintiff's legal theory fails common sense. Defendants' Opening Memorandum explained the absurdity of Plaintiff's supposed reliance on allegedly improper label statements that only an expert in the arcana of FDA regulations would recognize as improper. (Mem., 18:11-22:7.) Plaintiff relies on *Khasin*, 2012 U.S. Dist. LEXIS 161300, at *6, to argue that plausibility is a question of fact not to be decided on a motion to dismiss. Defendants respectfully assert that this is at odds with cases dismissing implausible claims at the pleadings stage.

Where, as here, it is clear from the allegations in the complaint that the alleged injury is implausible, it is appropriate to dismiss the claims on a 12(b)(6) motion. *See Reid*, 2012 U.S. Dist. LEXIS 133408, at *11-12 (finding, "even at the pleading stage, that it is not possible for the reasonable consumer to be deceived by Benecol's 'No Trans Fat' and 'No Trans Fatty Acids' labels" where the ingredient list showed that the product contains "a small amount of partially hydrogenated oils and trans fats"). While Plaintiff attempts to avoid the issue altogether by claiming that plausibility is a "fact issue," that argument is directly contrary to the Supreme Court's holding of *Iqbal*, requiring plaintiffs to *affirmatively demonstrate* facial plausibility to proceed on their claims. *See Ashcroft v. Iqbal*, 556 U.S. 662, 663 (2009). This is not a question of fact to be put off for another day—it is a threshold pleading requirement.

Ms. Maxwell's claims—based on hyper-technical alleged violations of FDA regulations—are not only inaccurate, but are also divorced from reality and implausible on their face. Let us consider what she is saying, for example, about having been misled by Defendants' statements about flavonoids. The tea package states that it "naturally contains tea flavonoids," and specifies that it contains "130 mg tea flavonoids." Ms. Maxwell claims that she believed that the product "met the minimum nutritional threshold to make such claims," and that she would not have purchased the products had she known it did not. (FAC ¶ 63.) The statement in question is truthful and accurate—Plaintiff does not allege otherwise. It is implausible that Ms. Maxwell or any other consumer would look beyond the truthful, plain meaning of this phrase. *See Kwikset*, 51 Cal. 4th at 326-27 n.10 (reliance "has always been understood to mean reliance on a statement for its *truth and accuracy*") (emphasis added).

In order to find the statement "contains" flavonoids misleading, Ms. Maxwell (and every class member) would have had to (i) be familiar with FDA regulations regarding use of phrases like "excellent source" and "good source," but unfamiliar with FDA regulations regarding "quantity claims;" (ii) believe that the use of the term "contains," without more, was the legal equivalent of claiming the products were a "*good* source" or "*excellent* source" of flavonoids; and (iii) conclude from this that the products contain more flavonoids than the claim at issue actually states they do (i.e., 130 mg per serving).

This argument is completely illogical. Anyone well versed enough in FDA regulations to know that implied nutrient content claims indicate the nutrient is present at a certain percentage of its RDI would also know that there *is no* RDI for "antioxidants." And anyone who read the label would see the exact quantity of flavonoids in the products. Plaintiff may not pick words off the label and try to state a claim by reading them out of context. *See Hairston v. S. Beach Beverage Co.*, No. CV 12-1429-JFW (DTBx), 2012 WL 1893818, at *5 (C.D. Cal. May 18, 2012).

There are simply no facts pled here that give rise to a plausible claim of reasonable consumer deception or injury. In both *Williams v. Gerber Prods. Co.*, 552 F.3d 934, 938-39 (9th Cir. 2008), and *Astiana v. Ben & Jerry's*, 2011 U.S. Dist. LEXIS 57348, the courts found questions of fact existed as to deception because the plaintiffs alleged that labels were misleading independent of FDA regulations. In *Williams*, plaintiffs alleged that products consisting mainly of corn syrup were represented as "fruit juice snacks," and in *Astiana*, plaintiffs alleged an ingredient was not disclosed on the label. Here, Plaintiff alleges no such thing. The labels are truthful. Moreover, none of Plaintiff's authorities dispense with the need to plead *facts* regarding reliance and deception. And it is no answer to say that alleged regulatory violations are actionable under UCL's "unlawful" prong even if deception is implausible. (Opp., 1:6-18.) Plaintiff must still plead plausible injury, which simply cannot arise from her regulatory claims. She builds her claims solely on alleged technical violations, seeking to impose a strict liability standard for regulatory violations. Courts have dismissed such claims on the pleadings as facially implausible. *See, e.g., Mason v. Coca-Cola Co.*, 774 F. Supp. 2d 699, 705 n.4 (D.N.J. 2011) ("It is simply not plausible that consumers would be aware of FDA regulations regarding 'nutrient content' and

restrictions on the enhancement of snack foods.")[6]; *Polk v. KV Pharm. Co.*, No. 4:09-CV-00588 SNLJ, 2011 U.S. Dist. LEXIS 144313 (D. Mo. Dec. 15, 2011) (violations of FDA's good manufacturing practices cannot cause injury). (*See* Mem., 19:1-12.)

C. Plaintiff Has Not Pled Her Case with the Requisite Particularity.

As shown in Defendants' Opening Memorandum, Plaintiff fails to plead her case with the particularity required by Rule 9(b). (Mem., 22:8-23:14.)[7] In response, Plaintiff points to the heft of her 46-page FAC as proof of specificity. (Opp., 20:7-8.) But lengthy repetition of conclusory allegations cannot mask the shallowness of the allegations actually pled. Plaintiff relies on *Khasin* to argue that Rule 9(b) raises questions of fact to be decided at a later time. *See Khasin*, 2012 U.S. Dist. LEXIS 161300, at *22-23. But Ninth Circuit precedent requires plaintiffs to plead which statements they relied on and found material. *Kearns v. Ford Motor Co.*, 567 F.3d 1120, 1126 (9th Cir. 2009). This is a threshold pleading requirement. Plaintiff's reliance on *Khasin* is misplaced because, here, Plaintiff alleges *changes* to labeling and websites, but never even specifies which statements she saw. She fails to clear Rule 9(b)'s high hurdle.

What: Plaintiff claims the "what" is "discrete types of unlawful and deceptive claims by Defendant," and lists the six categories of FDA regulations. (Opp., 20:10-14.) But she fails to allege which products are at issue for each type of claim, which label or website statements she read and relied on, or whether (and why) they were material to her. *See Kearns*, 567 F.3d at 1126

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[6] Plaintiff asserts her claims are more specific than those of the plaintiffs in *Mason* who "vaguely alleg[ed]" that Defendant's products were not "healthy," (Opp., 16:27). However, *Mason* plaintiffs, just like Ms. Maxwell, actually alleged "nutrient content" claim violations because the product allegedly did not meet the criteria to make such claims. (*Compare Mason*, Third Amended Compl., Dkt. No. 35 *with* FAC ¶ 53.) Plaintiff says that *Polk* involved a consent decree between defendants and the FDA (Opp., 17:14-15), but never explains why that matters. She says *Chavez* is irrelevant because that involved a "lack of substantiation" theory (*id.* at 7 n.3), yet Plaintiff also alleges lack of substantiation. (*Cf.* FAC ¶ 69.) None of her arguments explain away the holdings of these cases.

[7] Plaintiff argues that Rule 9(b) does not apply to her UCL claim because fraud is not an essential element of her claim. (Opp., 21:6-16.) Plaintiff misstates the law. As *Vess v. Ciba-Geigy Corp. USA*, 317 F.3d 1097, 1103-04 (9th Cir. 2003), makes clear, where the crux of the complaint is premised on a uniform course of fraudulent conduct, every claim must be pled with particularity. Here, Plaintiff contends that Defendants engaged in a "scheme" where "Plaintiff and the Class … were the intended targets of such representations." (FAC ¶¶ 205-206.)

(plaintiff failed to plead which statements he relied on and found material). For example, Plaintiff alleges that she "saw such health related claims on Unilever's website and relied on Defendants' health claims which influenced her decision to purchase the Defendants' products." (FAC ¶ 126.) Which "health claims"? Which website pages? Which products?

When: She claims the "when" is "since 2008 and throughout the Class Period." (Opp., 20:14-15.) But she fails to allege specific dates of purchase. *Yumul v. Smart Balance, Inc.*, 733 F. Supp. 2d 1117, 1124 (C.D. Cal. 2010) ("'repeatedly' during the class period" not specific enough). And while she claims the statements on labels and websites changed throughout the class period, she fails to state which of these statements she saw and how often she purchased the product. *Briseno v. ConAgra Foods, Inc.*, No. CV 11-05379 MMM (AGRx), 2011 U.S. Dist. LEXIS 154750, at *37-38 (C.D. Cal. Nov. 23, 2011); *see also Yumul*, 733 F. Supp. 2d at 1124.

Where: Plaintiff claims the "where" is "Defendant's package labels and product websites." (Opp., 20:16.) Besides lacking specificity, this allegation fails to state where she purchased the product. *See Edmunson v. Procter & Gamble Co.*, No. 10-CV-2256-IEG (NLS), 2011 U.S. Dist. LEXIS 53221, at *16-17 (S.D. Cal. May 17, 2011) (UCL and CLRA claims dismissed where plaintiff failed to allege where plaintiff purchased the products at issue).

How: Plaintiff claims the "how" is that Defendants violated the Sherman Law, Plaintiff purchased the products in reliance on the "misrepresentations," and thus was deceived. (Opp., 20:17-23.) But she never alleges what she believed the statements to mean pre-purchase or that she failed to receive health benefits. Worse, she never explains how the *regulatory* status of an otherwise perfectly fine product caused her to lose the benefit of her bargain.[8] *See Briseno*, 2011 U.S. Dist. LEXIS 154750, at *36-37 (not enough that plaintiff alleged he believed the label, would not have purchased the product but for that representation, and lost money as a result).

[8] Plaintiff fails to plead causation, simply saying she "explain[ed] the causal connection between Defendants' misrepresentations and her economic injuries." (Opp., 20 n.9.)

D. All of Plaintiff's Claims Are Preempted.

1. Plaintiff's Attempts to Impose Requirements "Not Identical" to FDA Regulations Are Expressly Preempted.

Defendants showed in their Opening Memorandum that Plaintiff seeks to impose requirements that are "not identical" to FDA regulations. That violates Section 343-1(a), the "express preemption" provision of the FDCA. (*See* Mem., 14:17-18:7.) Rather than demonstrate how her claims are "identical," she repeats her reference to *Khasin* and offers this Court only the conclusory assurance that they are. But Defendants respectfully assert that such conclusory allegations are not enough—courts routinely probe behind those assertions to determine whether plaintiffs have stated a plausible claim for imposing identical regulations. *See, e.g., Carrea*, 2011 U.S. Dist. LEXIS 6371, at *11 (N.D. Cal. Jan. 10, 2011) (rejecting plaintiff's allegations, based on FDA warning letters, that label violated FDA regulations); *Wyeth v. Levine*, 555 U.S. 555, 570 (2009) (analyzing whether a product was a "new drug" under the FDCA).

Moreover, Ms. Maxwell asserts different regulatory arguments that cannot be considered "identical" to FDA and state regulations. First, her claims depend on concluding that "source of" flavonoids, for example, is a nutrient content claim, but her only support is an FDA warning letter that does not carry the force of law. (Opp., 7:14-8:7.) The fact is that a statement is a nutrient content claim only if it "characterizes the level of any nutrient." 21 U.S.C. § 343(r)(1)(A). Explaining that a product is a source of a nutrient does not characterize the *level* of that ingredient.[9]

Second, Plaintiff tries to support her challenges to "natural" statements by again citing non-binding warning letters. (Opp., 8:8-14.) But she selectively rejects other FDA commentary, such as statements that citric acid can be consistent with "natural" claims. Nor does she explain why these complex and scientific matters should be decided by the Court instead of FDA. In *Astiana v. Hain Celestial*, --F. Supp. 2d--, 2012 U.S. Dist. LEXIS 165368, at *9, Judge Hamilton

[9] Plaintiff tries to salvage additional claims that she cites from the website, but nowhere alleges whether she saw or relied on these claims. Plaintiff herself cannot keep track of which statements are at issue as she refers to "excellent source" claims in her Opposition that were never mentioned in the FAC. (Opp., 8:4-5.)

refused to allow plaintiffs to impose their own definition of "all natural" on products comprehensively regulated by FDA. (*See* Ex. B.) FDA's decision not to create "natural" regulations coupled with extensive FDA regulation of the products' labels led the Court to dismiss plaintiffs' complaint. *Id.* at *7-9. The same reasoning applies here.

Finally, Plaintiff complains that Defendants did not address every single "health" claim allegation appearing in the FAC. (Opp., 8:15-26.) But she herself never alleges to have seen and relied on each of the alleged representations. Even if she had, the website statements are not "health claims;" they simply discuss current research and the effect of a substance on the structure or function of the body, 21 U.S.C. § 321(g)(1)(C). For example, the website references research showing that drinking green tea can lower cholesterol. (FAC ¶ 117.) This reference to current research does not constitute a "health" claim that would render tea a *drug*. Plaintiff's attempt to stretch FDA regulations beyond their plain meaning and common sense must fail.

Ms. Maxwell cannot mask the fact that she seeks to go beyond current federal regulations. Because her claims are unsupported by law, she attempts to bolster her argument with warning letters and a rejected "health claim" application concerning tea and cardiovascular disease. But warning letters are not legal authority, and an application for an irrelevant health claim is immaterial to Defendants' lawful statements. And because rewriting FDA regulations is not allowed, she characterizes her case as simply applying "objective criteria" from FDA sources, as in *Delacruz*, where the court found that "certain of Plaintiff's claims now *allude* to FDA regulations." *Delacruz v. CytoSport, Inc.*, No. C 11-3532 CW, 2012 U.S. Dist. LEXIS 90847, at *28 (N.D. Cal. June 28, 2012). But Plaintiff's only theory of the case is that the labels are misleading *because* they violate technical regulations that she misinterprets to fit her argument.

2. There is No Private Right of Action to Enforce FDA Regulations.

In their Opening Memorandum, Defendants showed that FDCA Section 337(a) precludes a private right of action to enforce violations of FDA regulations. (Mem., 9:9-13:11.) *See Pom*

Wonderful LLC v. Coca-Cola Co., 679 F.3d 1170, 1175-76 (9th Cir. 2012)[10]; *All One God Faith, Inc. v. Hain Celestial Grp., Inc.*, No. C 09-3517 SI, 2012 U.S. Dist. LEXIS 111553, at *33 (N.D. Cal. Aug. 8, 2012).[11] Citing *Khasin*, Plaintiff disagrees, but this position conflicts with the more recent decision in *Astiana v. Hain Celestial*, --F. Supp. 2d--, 2012 U.S. Dist. LEXIS 165368.

In that case, the court dismissed CLRA, UCL, and FAL claims based on "all natural" labels, finding *Pom* "especially instructive." *Id.* at *2-3. The Court ruled that plaintiffs could not argue that "all natural" claims were misleading due to artificial or synthetic ingredients in cosmetics because the Ninth Circuit "found that Congress had entrusted the task of guarding against deception to the FDA." *Id.* at *4-5. The specific cause of action at issue in *Pom* was irrelevant. *See Chavez v. Nestle USA, Inc.*, No. CV 09-9192-GW (CWx), 2011 U.S. Dist. LEXIS 9773, at *24-25 (C.D. Cal. Jan. 10, 2011) (applying Lanham preemption analysis to UCL claims); *see also Braintree Labs, Inc. v. Nephro-Tech, Inc.*, No. 96-2459-JWL, 1997 U.S. Dist. LEXIS 2372, at *22 (D. Kans. Feb. 26, 1997) ("same concerns that militate against allowing the Lanham Act to serve as a vehicle for alleging FDCA violations attend the use of a common law cause of action").

Moreover, contrary to Plaintiff's argument (Opp., 6:7-9), the Ninth Circuit expressly rejected the notion that a defendant's compliance with FDCA matters. *See Pom*, 679 F.3d at 1178 (emphasis added); *see also Astiana v. Hain Celestial*, --F. Supp. 2d--, 2012 U.S. Dist. LEXIS 165368, at *3-6. Yet Plaintiff asks this Court to decide, in place of FDA, whether "source" claims are nutrient content claims and whether statements describing an ingredient's effect on the body

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[10] The court remanded the state law claims so the district court could correct its standing analysis and then proceed to its preemption analysis. *Pom*, 679 F.3d at 1178-79.

[11] *Brown v. Hain Celestial Grp., Inc.*, No. C 11-03082 LB, 2012 U.S. Dist. LEXIS 108561 (N.D. Cal. Aug. 1, 2012) is not at odds with *All One God Faith*. *Brown* found claims under state "organic" laws were not preempted based on a different statutory scheme regarding "organic" regulations. Under the Organic Foods Production Act, only state *certification* laws are preempted, *not* labeling. *Id.* at *25-26. Unlike the FDCA and NLEA, states may develop their own organic certification programs that impose more restrictive requirements. *Id.* at *12.

are "health claims" or "structure-function" claims. Without a conclusion on these regulatory issues, Plaintiff has no case.[12]

Plaintiff's entire case is built on cases that are distinguishable. Her authorities involve claims based on labels that are misleading *independent* of FDA regulations. Courts can handle these typical consumer deception cases without resorting to the interpretation of the FDCA. In contrast, Plaintiff's own claims are based 100% on FDA regulations. This difference is crucial—Plaintiff has no private right of action to usurp FDA's role to regulate labeling technicalities that have no nexus to consumer deception.[13]

A number of cases confirm that a complaint based solely on regulatory infractions does not pass muster. (*See* Mem., 13:15-14:15).[14] Plaintiff ignores these or dismisses them as involving pharmaceuticals. (Opp., 11:25-12:5.) But what Plaintiff cannot ignore is that, in trying to "privatize" FDCA enforcement, she has built her case entirely on regulatory technicalities. That is improper. *See, e.g., Verzani v. Costco Wholesale Corp.*, No. 09 Civ. 2117 (CM), 2010 U.S. Dist. LEXIS 107699, at *8-9 (S.D.N.Y. Sept. 28, 2010) ("persistent allegations that [the labeling] violates the FDCA … indicates that his true purpose is to privately enforce alleged violations of the FDCA, rather than to bring a claim for unfair and deceptive business practices").

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[12] In the alternative, the Court could find that this warrants dismissal under the doctrine of primary jurisdiction. *See Astiana v. Hain Celestial*, --F. Supp. 2d--, 2012 U.S. Dist. LEXIS 165368, at *5-7 (citing *Pom* and dismissing "natural" claims in deference to FDA).

[13] The Court in *Khasin* relied on additional cases involving express preemption of state tort claims related to medical devices. *See, e.g., Hughes v. Boston Scientific Corp.*, 631 F.3d 762 (5th Cir. 2011); *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008); *Wyeth*, 555 U.S. 555. Those cases dealt with physical harm caused by devices, and involved only state tort claims, not statutory claims predicated on violations of the FDCA. They do not undercut established principles of FDA deference. In fact, in *Riegel*, the Court affirmed the importance of deference to FDA and prevented FDA determinations from being second-guessed by a jury. *Id.* at 325.

[14] *Loreto v. Procter & Gamble Co.*, 737 F. Supp. 2d 909, 919 (S.D. Ohio 2010); *Sandoz Pharm. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 231 (3d Cir. 1990) (FDA guideline violations are insufficient, as there is no private right of action); *In re Epogen & Aranesp Off-Label Mktg. & Sales Practices Litig.*, 590 F. Supp. 2d 1282, 1290-91 (C.D. Cal. 2008) (Gutierrez, J.) (plaintiffs may not use other laws to assert a private cause of action that is based on violations of the FDCA); *Perez v. Nidek Co.*, 657 F. Supp. 2d 1156, 1166 (S.D. Cal. 2009) (Moskowitz, J.) (plaintiffs cannot "privately enforce the FDCA and its regulations under the guise of state law claims."); *In re Schering-Plough Corp. Intron/Temodar Consumer Class Action*, No. 2:06-cv-5774 (SRC), 2009 U.S. Dist. LEXIS 58900, at *47 (D.N.J. July 10, 2009) (plaintiffs may not "merely recite violations of the FDCA, for which there is no private cause of action").

Plaintiff's argument that her claims may be "based on" the Sherman Law, which has adopted the FDCA, is dependent on inapposite "bait-and-switch" cases, in which food products are "passed off" as a something they are not, thereby fooling consumers. Plaintiff relies on cases where grey farmed salmon was treated with undisclosed pink additives to make it appear to be wild (*Farm Raised Salmon Cases*, 42 Cal. 4th 1077 (2008)), where a product was falsely passed off as being bottled in New Mexico (*Chavez v. Blue Sky Natural Bev. Co.*, 268 F.R.D. 365, 372 (N.D. Cal. 2010), where a product was falsely represented to be "healthy," even though the Nutrition Facts panel belied that representation (*Delacruz*, 2012 U.S. Dist. LEXIS 90847 at *28, and where a product containing no milk was passed off as milk (*CytoSport, Inc. v. Vital Pharm., Inc.*, No. 2:08-CV-02632-JAM-GGH, 2012 WL 3881599 (E.D. Cal. Sept. 6, 2012)). This is classic consumer deception that has been historically within the purview of state law. Such claims, even if styled as UCL or CLRA claims, do not seek to "enforce" FDA regulations and exist independently of the FDCA.

This case is not about confusion, deception, or injury. It is about regulatory minutiae. Plaintiff has no "Plan B," no *non*-FDCA way of proving her case. Without a plausible claim that the labels were misleading, she simply seeks to take enforcement action that FDA has not.

E. Plaintiff's Claims All Fail for Other, Claim-Specific Reasons.

1. Plaintiff's UCL, CLRA, and FAL Claims Fail to State a Claim.

Defendants showed in their Opening Memorandum that Plaintiff's UCL, CLRA, and FAL claims fail to state a claim. (Mem., 23:16-24:8.) In opposition, Plaintiff begins with a lengthy recitation of UCL law. (Opp., 21:18-22:27.) But she fails to identify facts showing that she suffered "injury in fact" and "lost money or property" as a result of unfair competition.

Plaintiff's attempt to dismiss *Birdsong*, 590 F.3d 955, is unavailing. (Opp., 23:2-8.)[15] She asserts that unlike the plaintiffs in *Birdsong*, she has "already suffered cognizable damages." (*Id*.

[15] Plaintiff similarly fails to distinguish *In re Ferrero Litig*, 794 F. Supp. 2d 1107, 1112 (S.D. Cal. 2011) (Huff, J.) (no reliance) and *Whitson v. Bumbo*, No. C 07-05597 MHP, 2009 U.S. Dist. LEXIS 32282, at *18 (N.D. Cal. Apr. 15, 2009) (no injury).

at 23:7 (emphasis added).) But that just restates her legal conclusion—precisely the type of theoretical and speculative injury prohibited by *Birdsong*.

2. Plaintiff's Breach of Warranty Claims Should Be Dismissed.

First, Plaintiff makes no effort to show a "written warranty" under the MMWA or the Song-Beverly Act. (Mem., 24:12-19.) Ignoring all of Defendants' cited authorities, she never even states the meaning of "express warranty" under the statutes or why she thinks this definition is met. (Opp., 23:28-24:2.) Second, she fails to show that her Song-Beverly claim applies to consumables. (Opp., 24:4-6.) She claims it falls under Cal Civ. Code § 1793.35 which can be applied to consumables, but this provision merely specifies how a buyer may return goods "within 30 days of purchase or the period specified in the warranty." Third, her MMWA claim fails because she does not allege that she meets the required $5 minimum price for products (Mem., 24:22-23), and because a federal court does not have jurisdiction to hear a MMWA claim if "the number of plaintiffs is less than one hundred." 15 U.S.C. § 2310(d)(3)(C).

Plaintiff next contends that the MMWA is *not* inapplicable to warranties otherwise governed by federal law because she also pled California law in the FAC. (Opp., 24:19-22.) That begs the question. Plaintiff does not deny that the FDCA governs Defendants' labeling.

3. "Unjust Enrichment" is Not a Cause of Action in California.

Plaintiff says her unjust enrichment claim should be allowed because there is a split of authority. (Opp., 24:24-26.) But the California Court of Appeals has recently clarified "[u]njust enrichment is not a cause of action, just a restitution claim." *Williamson v. Reinalt-Thomas Corp.*, No. 5:11-CV-03548 LHK, 2012 U.S. Dist. LEXIS 58639, at *13-14 (N.D. Cal. Apr. 25, 2012) (citations omitted); *see also Williamson v. Apple, Inc.*, No. 5:11-cv-00377 EJD, 2012 U.S. Dist. LEXIS 125368, at *27 (N.D. Cal. Sept. 4, 2012). Even if the Court were to allow this type of claim, it would still flunk the heightened pleading requirements of Rule 9(b). *See Oestreicher v. Alienware Corp.*, 544 F. Supp. 2d 964, 975 (N.D. Cal. 2008); *supra* at Section C.

III. CONCLUSION

For all the foregoing reasons, Defendants respectfully request that the Court dismiss the First Amended Complaint with prejudice or, in the alternative, grant the motion to strike.

Dated: November 30, 2012

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